# A post-authorisation safety study of ABRYSVO in immunocompromised, or renally or hepatically impaired adults aged 60 years and older in a real world setting in Europe and UK (C3671038)

**First published:** 21/02/2025

**Last updated:** 06/11/2025

Study Ongoing

## Administrative details

**EU PAS number**

EUPAS1000000400

**Study ID**

1000000400

**DARWIN EU® study**

No

**Study countries**

- [ ] France
- [ ] Spain

United Kingdom

**Study description**

As immunocompromised, renally and hepatically impaired older adults were not included in clinical trials that supported regulatory approvals, the safety profile of ABRYSVO in these populations is unknown. This protocol describes a post-authorization safety study (PASS) to assess the safety of ABRYSVO in immunocompromised, or renally or hepatically impaired adults aged 60 and older in select European countries and in the UK, with data sources that can capture vaccine exposure in the target populations, and where outcomes and key covariates can be ascertained.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### Pfizer

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

### Julius Clinical Research

Netherlands

**First published:** 02/03/2021

**Last updated:** 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

## University Medical Center Utrecht (UMCU)

☐ Netherlands

**First published:** 24/11/2021

**Last updated:** 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

## Analysis Group, Inc.

# Networks

## Vaccine monitoring Collaboration for Europe (VAC4EU)

☐ Belgium
☐ Denmark
☐ Finland
☐ France
☐ Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

**First published:** 22/09/2020

**Last updated:** 22/09/2020

Network | Outdated | ENCePP partner

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Cynthia de Luise

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/03/2024

Actual: 01/03/2024

**Study start date**
Planned: 31/03/2025

Actual: 01/10/2025

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**Data analysis start date**
Planned: 01/11/2028

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**Date of interim report, if expected**
Planned: 30/09/2026

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**Date of final study report**
Planned: 28/09/2029

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Pfizer 100%

## Study protocol

C3671038_RSV VACCINE OLDER ADULT PROTOCOL V1.0_09JUL2024.pdf

(1016.93 KB)

C3671038_RSV VACCINE OLDER ADULT UPDATED PROTOCOL V2.0_07OCT2024.pdf (1 MB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Other study registration identification numbers and links

C3671038

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study design:**

A retrospective comparative cohort design will serve as the primary study design.

In addition to the primary study design (i.e, comparative cohort design), for an appropriate subset of the study outcomes, the self-controlled risk interval (SCRI) design will also be used.

**Main study objective:**

To estimate the incidence rates and rate ratios of safety events of interest in immunocompromised, or renally or hepatically impaired adults aged 60 years and older who receive ABRYSVO compared to a relevant comparator group who does not receive ABRYSVO (evaluated as separate populations and if appropriate, as a combined population).

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

ABRYSVO

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

# Population studied

**Short description of the study population**

The target population will consist of individuals who are immunocompromised, or renally or hepatically impaired (evaluated as separate populations and if appropriate, as a combined population) who are at least 60 years of age on the date of vaccination (i.e, index date for the vaccinated cohort) or on the matched index date (for the unvaccinated cohort), and who have at least 12 months of medical history in one of the data sources with no record of RSV vaccination in that 12 month period and who have at least one day of post-index follow up. Immunocompromised or renally impaired or hepatically impaired status will be ascertained via coded diagnoses, treatments, procedures, and/or laboratory values, as appropriate, at index date or in the 12-month baseline period prior to the index date.

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**Age groups**

- Adults (18 to < 65 years)
- Elderly (≥ 65 years)

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**Special population of interest**

Hepatic impaired

Immunocompromised

Renal impaired

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**Estimated number of subjects**

2356

# Study design details

**Setting**

The study will be conducted in a source population of the participating population-based electronic healthcare data sources from the VAC4EU network.

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**Comparators**

To be included in the unvaccinated cohort, individuals must meet the following criteria:

- No vaccine record on index date: They must not have a record of receiving any vaccine, including the RSV vaccines, on the index date.
- No RSV vaccination in baseline period: They must not have a record of receiving any RSV vaccine during the 12-month baseline before the index date.

For the SCRI design, person-time in the risk interval will be considered “exposed,” while person-time in the control interval will be considered “unexposed.”

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**Outcomes**

Acute disseminated encephalomyelitis; diabetes mellitus type I; Guillain-Barré syndrome; narcolepsy; thrombocytopenia (idiopathic); thrombosisthrombocytopenia syndrome; acute cardiovascular injury; arrhythmia; coronary artery disease; heart failure; microangiopathy; myocarditis and pericarditis; stress cardiomyopathy; coagulation disorders: disseminated intravascular coagulation, venous thromboembolism (pulmonary embolism, deep vein thrombosis), thrombotic microangiopathy, cerebral venous thrombosis, thrombotic thrombocytopenia syndrome, ischemic stroke, myocardial infarction, haemorrhage; single organ cutaneous vasculitis; thrombocytopenia with venous thromboembolism; Bell’s palsy; generalised convulsion; meningoencephalitis; transverse myelitis; acute respiratory distress syndrome; erythema multiforme; anaphylaxis; death (any causes)

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**Data analysis plan**

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor and PI.

The SAP may modify the plans outlined in the protocol; any major modifications of primary endpoint definitions or their analyses will be reflected in a protocol amendment.

The SAP will also provide additional detail regarding the evaluation of a threshold of excess risk for each of the outcomes of interest.

This will be determined based on background incidences for each event, in addition to prespecified significance level (e.g., alpha = 0.01 or 0.05) and power. All analyses will be conducted using R version R-4.0.3 or higher.

The SAP will contain additional detail of the data analysis and meta-analysis. One interim analysis and report may be conducted. The interim report will be limited to descriptive analyses. Comparative analyses will be included in the final report. Further details will be described in the SAP.

All analyses will be conducted separately for the 3 populations of interest: immunocompromised, renally impaired, or hepatically impaired; and if appropriate, in the combined population.

Prior to any combined analysis, a Higgin’s I2 statistic will be used to assess the heterogeneity in the primary outcomes across the 3 populations of interest.

If the percentage of heterogeneity estimated by I2 is high (e.g., >50%; specific threshold to be specified in the SAP), a combined effect may be estimated using adapted methods such as a random-effects model.

# Documents

**Study report**

c3671038-progress-report1-report-body.pdf (1.18 MB)

# Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

**Data source(s)**

Clinical Practice Research Datalink (CPRD) GOLD

The Valencia Health System Integrated Database

The Information System for Research in Primary Care (SIDIAP)

EpiChron Cohort

Système National des Données de Santé (French national health system main database)

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

Population registry

## Use of a Common Data Model (CDM)

**CDM mapping**

Yes

**CDM Mappings**

**CDM name**

ConcepTION CDM

**CDM website**

https://www.imi-conception.eu/

**CDM release frequency**

6 months

## Data quality specifications

**Check conformance**

Yes

**Check completeness**

Yes

**Check stability**

Yes

**Check logical consistency**

Yes

## Data characterisation

## Data characterisation conducted

No